

# EXHIBIT 20

1           IN THE UNITED STATES DISTRICT COURT  
2           FOR THE NORTHERN DISTRICT OF OHIO  
3           EASTERN DIVISION

- - -

4           IN RE: NATIONAL                   : HON. DAN A.  
5           PRESCRIPTION OPIATE           : POLSTER  
6           LITIGATION                    :  
7   :  
8           APPLIES TO ALL CASES           : NO.  
9   : 1:17-MD-2804  
10    :

11                   - HIGHLY CONFIDENTIAL -

12           SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

13                   VOLUME II

14                   - - -

15                   March 8, 2019

16                   - - -

17                   Continued videotaped  
18           deposition of MICHELE R. DEMPSEY, taken  
19           pursuant to notice, was held at the law  
20           offices of Drinker Biddle & Reath, 105  
21           College Road East, Princeton, New Jersey,  
22           beginning at 10:15 a.m., on the above  
23           date, before Michelle L. Gray, a  
24           Registered Professional Reporter,  
25           Certified Shorthand Reporter, Certified  
26           Realtime Reporter, and Notary Public.

- - -

27                   GOLKOW LITIGATION SERVICES  
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18 (Ropes & Gray - via telephone)

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24

I N D E X

Testimony of:

MICHELE R. DEMPSEY

By Mr. Janush 427, 736

By Mr. Barker 579

E X H I B I T S

NO.	DESCRIPTION	PAGE
Janssen Dempsey-23	E-mail Thread 4/13/18 Subject, Review Controlled Substance Analytics JAN-MS-05444681-92	427
Janssen Dempsey-24	E-mail Thread 6/8/18 Subject, Controlled Substances Project JAN-MS-05444730-37	435

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	Janssen		
7	Dempsey-25	Controlled Substances Suspicious Order Monitoring Program Questionnaire JAN-MS-02960654-19	446
8			
9			
10	Janssen		
11	Dempsey-26	Evaluation of the Suspicious Orders Monitoring System For J&J (Woodworth) JAN-MS-05444748-63	455
12			
13			
14	Janssen		
15	Dempsey-27	E-mail Thread 2/6/18 Subject, Question JAN-MS-05444648-65	489
16			
17	Janssen		
18	Dempsey-28	E-mail Thread 2/16/18 Subject, Report Change JAN-MS-05444781-82	498
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20			
21	Janssen		
22	Dempsey-29	Evaluation of the Suspicious Monitoring System for J&J JAN-MS-0544783-98	500
23			
24			

1 - - -

2 THE VIDEOGRAPHER: We are  
3 now on the record. My name is  
4 Henry Marte. I'm a videographer  
5 with Golkow Litigation Services.

6 Today's date is March 8,  
7 2019, and the time is 10:15 a.m.

8 This videotaped deposition  
9 is being held in Princeton, New  
10 Jersey, in the matter of National  
11 Prescription Opiate Litigation.

12 This is Day 2 of the  
13 deposition of Michele Dempsey.

14 All appearances are noted on  
15 the stenographic record.

16 Will the court reporter  
17 please re-administer the oath.

18 - - -

19 ... MICHELE R. DEMPSEY,  
20 having been first duly sworn, was  
21 examined and testified as follows:

22 - - -

23 CONTINUED EXAMINATION

24 - - -



1 BY MR. JANUSH:

2 Q. Hi, Ms. Dempsey. How are  
3 you today?

4 A. Good. Thank you.

5 Q. Thank you for appearing for  
6 Day 2 of your deposition.

7 When we last broke at the  
8 conclusion of the January 22, first date  
9 of your deposition, we were talking about  
10 the audit that had been performed of  
11 your -- or Janssen's suspicious order  
12 monitoring system.

13 Do you remember that?

14 A. Yes.

15 Q. And I'm going to mark a new  
16 document as Dempsey Exhibit 23.

17 MR. JANUSH: Copies to you,  
18 your counsel.

19 (Document marked for  
20 identification as Exhibit  
21 Janssen-Dempsey-23.)

22 MR. BARKER: Evan, just for  
23 clarification, this is a  
24 collective exhibit? There are a

1 the HDMA conferences where they have a  
2 special track on compliance items like  
3 suspicious order monitoring where DEA  
4 speaks to distributors.

5 Q. What was your title when you  
6 took over responsibilities for Janssen's  
7 suspicious order monitoring?

8 A. Director of controlled  
9 substance compliance.

10 Q. Okay. And is that still  
11 your title today?

12 A. Yes.

13 Q. I'd like to discuss the  
14 evolution of the Janssen suspicious order  
15 monitoring program in more detail.

16 When you first became  
17 involved in Janssen's suspicious order  
18 monitoring program, what was your  
19 understanding as to when that program  
20 came into being?

21 A. I learned that the algorithm  
22 that was currently being used was  
23 implemented in 2006.

24 Q. Okay. And do you have an

1 understanding as to whether there was a  
2 program in place to monitor potentially  
3 suspicious orders before that one?

4 A. I was aware that in the  
5 previous year there was a manual process.

6 MR. BARKER: Okay. Let's  
7 mark as Exhibits 42-A, B, and C.

8 (Document marked for  
9 identification as Exhibit  
10 Janssen-Dempsey-42-A.

11 (Document marked for  
12 identification as Exhibit  
13 Janssen-Dempsey-42-B.

14 (Document marked for  
15 identification as Exhibit  
16 Janssen-Dempsey-42-C.)

17 MR. BARKER: Documents that  
18 begin with the Bates Numbers  
19 JAN-MS-03741177 running through  
20 41200. 42-B is JAN-MS-0374110  
21 running through 76, and 42-C is  
22 374 -- excuse me, JAN-MS-03741201  
23 through 05.

24 BY MR. BARKER:

1 A. Yes.

2 Q. Did DEA give any specific  
3 advice relating to your suspicious order  
4 monitoring program, including whether  
5 there were any deficiencies or  
6 improvements that could be made?

7 A. No. And if you look at the  
8 end, in closing. He said no --

9 Q. You're saying the end.  
10 Where are you looking?

11 A. Page 4.

12 Q. Page 4. Okay.

13 A. Closing.

14 Q. So what is the -- what is  
15 closing? What are we talking about here?

16 A. This is what Billy Lane  
17 said.

18 Q. Okay. Billy Lane is one of  
19 the two DEA agents?

20 A. He was the lead inspector.

21 Q. Okay. So Mr. Lane told you  
22 what?

23 A. "No violations of the  
24 C.F.R." But he said the audit came out

1 fine.

2 Q. Okay. And again, as  
3 Mr. Janush pointed out multiple times  
4 before, the suspicious order monitoring  
5 regulations are in the C.F.R.s, correct?

6 A. Yes.

7 Q. And then let's go to the top  
8 of the next page too, please. It also  
9 says, "No actions for their part."

10 Does that mean that there  
11 were no violations or any other action  
12 taken by the DEA?

13 A. That Billy Lane said that  
14 they were not taking any actions.

15 Q. Okay. And BL is Billy Lane?

16 A. Yes.

17 Q. Okay. Did Billy Lane say  
18 that he likes coming to facilities like  
19 the Kentucky distribution center?

20 A. He says that, "Overall likes  
21 coming to places like this."

22 Q. And did he have any comments  
23 on your recordkeeping systems?

24 A. We had -- we asked him how

1 Q. Got it. So the subject  
2 line, although it says 28 January, 2014,  
3 it's actually 2015 --

4 A. Yes.

5 Q. -- as reflected in the body.  
6 Okay. And at the top line  
7 it says, "The DEA just left, there were  
8 no observations."

9 What does that tell you  
10 about this particular inspection?

11 MR. JANUSH: Objection.

12 MR. BARKER: Strike that.

13 BY MR. BARKER:

14 Q. Do you have an understanding  
15 of what the result of the inspection was  
16 on or about January 28th of 2015?

17 A. As it's explained here, that  
18 from the time period that they audited,  
19 which was August 18, 2014, through that  
20 January, all the documentation and all  
21 the processes they reviewed, there was --  
22 there were no observations. Everything  
23 was good.

24 Q. Okay. And if we go to Page

1 inspection that you were just looking at  
2 in Exhibit 50?

3 A. The dates match.

4 Q. And what was the result of  
5 that inspection by the New Jersey  
6 Newark -- strike that.

7 What was the result of the  
8 inspection by the Newark, New Jersey  
9 office of the DEA at the Franklin  
10 distribution center?

11 A. There were zero  
12 observations.

13 Q. Okay. You're seeing that  
14 here?

15 A. Yes.

16 Q. And what does zero  
17 observations mean?

18 A. They did not find any  
19 noncompliance during their audit of the  
20 FDC.

21 Q. When was the next inspection  
22 that occurred of a Janssen facility that  
23 you're aware of?

24 A. I am guessing two years

1           communicate that he had any  
2           response from DEA.

3   BY MR. BARKER:

4           Q.     Okay. And certainly not  
5   part of his report, which we saw here in  
6   Exhibit 52, correct?

7           A.     Right.

8           Q.     The result of the inspection  
9   was what?

10          A.     Zero observations.

11          Q.     Zero observations. Meaning  
12   that they had no criticisms or  
13   corrections for your distribution  
14   facility, correct?

15          A.     Correct.

16          Q.     I'm going to mark as the  
17   next exhibit a document beginning Bates  
18   JAN-MS-03124010 going through 4011.

19                   MR. BARKER: We're marking  
20   this as Exhibit 54.

21                   (Document marked for  
22   identification as Exhibit  
23   Janssen-Dempsey-54.)

24   BY MR. BARKER:



1     you for correcting me. Who was the lead  
2     investigator?

3             A.     B. Morgan Freeman.

4             Q.     And who is the other  
5     investigator this time?

6             A.     Jason Smith.

7             Q.     The same one who had been  
8     there in 2013, right?

9             A.     Yes.

10            Q.     Okay. And so this was eight  
11    days after the SOP had been provided by  
12    Mr. Helfrick, as we saw in Exhibit 53,  
13    correct?

14            A.     Correct.

15            Q.     He provided that on the  
16    20th. And now they are back on the 28th?

17            A.     Yes.

18            Q.     Were there any issues found  
19    by the DEA in its follow-up inspection on  
20    December 28th of 2017 at the Kentucky  
21    distribution center?

22            A.     Going to the summary, there  
23    were zero observations, no issues.

24            Q.     So again, they had no

1 criticisms or comments on what they had  
2 been provided, correct?

3 A. Correct.

4 MR. BARKER: Next document  
5 that I'm going to provide you was  
6 one previously marked at your  
7 deposition as Exhibit 19.

8 BY MR. BARKER:

9 Q. It begins with  
10 JAN-MS-2987651, running through 7656.

11 Do you have Exhibit 19 in  
12 front of you?

13 A. Yes, I do.

14 Q. Do you recall Mr. Janush  
15 questioning you about this document?

16 A. Yes, I do.

17 Q. Okay. So I want to direct  
18 your attention to the second page of the  
19 document. And to the comment for DM-3.  
20 Are you DM-3 for purposes of this  
21 document?

22 A. Yes.

23 Q. How do you know that?

24 A. It's Dempsey, Michele. My

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, MICHELE R. DEMPSEY, have the opportunity to read and sign the deposition transcript.



MICHELLE L. GRAY,  
A Registered Professional  
Reporter, Certified Shorthand  
Reporter, Certified Realtime  
Reporter and Notary Public  
Dated: March 13, 2019

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